Claims

1. A human or animal non-totipotent cell, comprising at least one nucleic acid coding for at least one immune modulator under the control of a gene expression system which can be regulated by adding an active substance.

2. The cell as claimed in claim 1, characterized in that the cell is a stem cell, a precursor cell and/or an immortalized cell.

3. The cell as claimed in claim 1 or 2, characterized in that it is a pluripotent or multipotent embryonic, fetal, neonatal or adult stem cell.

4. The cell as claimed in at least one of claims 1 to 3 in the form of a cell line.

5. The cell as claimed in at least one of claims 1-4, characterized in that the gene expression system which can be regulated is a progesterone gene expression system, a tetracycline expression system and/or a rapamycin gene expression system.

6. The cell as claimed in at least one of claims 1-5, characterized in that the immune modulator has at least one of the following functional properties:

   a. inhibition of an antigen recognition mediated by T cells,

   b. inhibition of a signal mediated via a receptor on a T cell,

   c. activation of a signal mediated via a receptor on a T cell,

   d. inhibition of the growth of T cells,

   e. inhibition of molecules supporting the survival of T cells,

   f. inhibition of effector molecules of T cells (such as TNF-alpha, IFN-gamma),

   g. inhibition of the adhesion of T cells,

h. inhibition of a T cell-costimulatory interaction (activation of a lymphocyte takes place via two signals: firstly, a stimulation via the antigen receptor takes place, secondly, another signal for clonal expansion and differentiation of a non-imprinted lymphocyte occurs; this costimulatory interaction may be inhibited by an immune modulator),

i. inhibition of the activation, proliferation, survival, antigen presentation, signaling, and/or the effector functions of further cells involved in an immune response, such as, for example, common and special antigen-presenting cells, in particular, for example, dendritic cells and monocyte/macrophage B cells, neutrophilic granulocytes and NK cells, inhibition of the cellular interaction of different cells, either via surface receptors or via secreted molecules such as, for example, cytokines, chemokines or growth factors, which are involved in an immune response, such as, for example, common and special antigen-presenting cells, in particular, for example, dendritic cells and monocytes/macrophages, T cells, B cells, neutrophilic granulocytes and NK cells,

j. inhibition of the migration of cells involved in an immune response, such as, for example, special antigen-presenting cells, in particular, for example, dendritic cells and monocytes/macrophages, T cells, B cells, neutrophilic granulocytes and NK cells,

k. inhibition of components of the complement system,

l. inhibition of phagocytotic activities in connection with the presentation of foreign or autoimmune antigens, or by binding of antibodies to antigens, and/or

m. inhibition of inflammatory reactions.

7. The cell as claimed in at least one of claims 1 to 6, characterized in that the immune modulator is an antibody.

8. The cell as claimed in at least one of claims 1 to 6, characterized in that the immune modulator is

d. a receptor,
e. a soluble secreted receptor,
f. a secreted protein or peptide.

9. The cell as claimed in claim 8, in which the immune modulator is a fusion protein of a mutated IL 15 and an Fc fragment, said Fc fragment being fused to the C terminus of the mutated IL 15 molecule, preferably via the hinge region.

10. The cell as claimed in claim 9, characterized in that the Fc fragment of the antibody is an Fc fragment of an IgG, in particular of a human IgG1, IgG2, IgG3, IgG4 or an analogous mammalian IgG or an IgM, in particular a human IgM or an analogous mammalian IgM.

11. The cell as claimed in at least one of claims 1 to 10, characterized in that the nucleic acid additionally encodes a selection cassette, in particular a suitable transfection marker gene and/or differentiation marker gene.

12. The cell as claimed in at least one of claims 1 to 11, characterized in that the nucleic acid additionally encodes a molecule which inhibits NK cells and/or killer cells.

13. The cell as claimed in at least one of claims 1-11, characterized in that the nucleic acid additionally encodes a molecule which inhibits
a. dendritic cells,
b. monocytes and/or macrophages,
c. B cells,
d. polymorphonuclear cells, for example neutrophilic granulocytes.

14. The cell as claimed in claim 13, characterized in that said inhibitory molecule is a human MHC class I molecule, a chimeric MHC class I molecule or a viral MHC class I homolog.

15. A nucleic acid, coding for at least one immune modulator and at least one gene expression system which can be regulated by adding an active substance.

16. A vector, comprising at least one nucleic acid as claimed in claim 15.

17. A medicament, comprising at least one cell as claimed in any of claims 1 to 14 and suitable expedients and/or additives.

18. A human or animal organ-specific tissue and/or a human or animal mammalian organ, comprising at least one cell as claimed in any of claims 1 to 14.

19. A transgenic nonhuman mammal, comprising at least one cell as claimed in any of claims 1 to 14.

20. The use of a cell as claimed in any of claims 1 to 14 and/or of a human or animal organ-specific tissue and/or of a human or animal mammalian organ as claimed in claim 18 for transplantation into a human or animal mammal.

21. The use as claimed in claim 20, characterized in that it is an allo-, auto- or xenotransplantation.

22. The use of a cell as claimed in any of claims 1 to 14, of a nucleic acid as claimed in claim 15, of a human or animal organ-specific tissue and/or of a human or animal mammalian organ as claimed in claim 18 for preparing a medicament for inhibiting transplant rejection in a human or animal mammal, where appropriate in the presence of at least one immune modulator.

23. The use of a cell as claimed in any of claims 1 to 14, of a nucleic acid as claimed in claim 15, of a human or animal organ-specific tissue and/or of a human or animal mammalian organ as claimed in claim 18 for preparing a medicament for the prophylaxis and/or therapy of diseases resulting from a transplant and/or of autoimmune diseases.

24. A process for preparing a cell as claimed in any of claims 1 to 14, which process comprises the following steps:

c. introducing at least one nucleic acid as claimed in claim 15 and/or at least one vector as claimed in claim 16 into a transplantable human or animal non-totipotent cell, and

d. expressing said nucleic acid with addition of at least one suitable active substance for regulating the gene switch.

25. An *in vitro* process for preparing a human or animal organ-specific tissue and/or a human or animal mammalian organ as claimed in claim 18, which process comprises the following steps:

e. introducing both at least one nucleic acid as claimed in claim 15 and/or at least one vector as claimed in claim 16 and as well at least one differentiation marker gene into at least one non-totipotent stem cell, a non-totipotent precursor cell and/or a non-totipotent immortalized cell,

f. differentiating the cell of step a.,

g. selecting the differentiated cell of step b., and

h. introducing the selected cell of step c. into a human or animal organ-specific tissue and/or into a human or animal mammalian organ.

26. The process as claimed in claim 25, characterized in that, after, before or simultaneously with step a., at least one suitable transfection marker gene is introduced into at least one non-totipotent stem cell, a non-totipotent precursor cell and/or a non-totipotent immortalized cell and, after step a., the transfected cell of step a. is selected preferentially.

27. The process as claimed in either of claims 25 and 26, characterized in that the stem cell is a pluripotent or multipotent embryonic, fetal, neonatal or adult stem cell.

28. A process for generating a transgenic nonhuman mammal as claimed in claim 18, which process comprises the following steps:

f. introducing both at least one nucleic acid as claimed in claim 15 and/or at least one vector as claimed in claim 16 and at least one suitable transfection marker gene into at least one oocyte, stem cell, precursor cell and/or immortalized cell of a nonhuman mammal,

g. selecting the transfected cell of step a.,

h. introducing the cell selected according to step b. into at least one nonhuman mammalian blastocyst,

i. introducing the blastocyst of step c. into a nonhuman mammalian foster mother, and

j. identifying the transgenic nonhuman mammal developed from said

blastocyst.

29. The process as claimed in claim 28, characterized in that the stem cell is a pluripotent or multipotent embryonic, fetal, neonatal or adult stem cell.

30. A process for generating a transgenic nonhuman mammal as claimed in claim 19, which process comprises the following steps:

d. introducing both at least one nucleic acid as claimed in claim 15 and/or at least one vector as claimed in claim 16 and at least one suitable transfection marker gene into either of the two pronuclei of a fertilized nonhuman mammalian oocyte,

e. introducing the mammalian oocyte of step a. into a nonhuman mammalian foster mother, and

f. identifying the transgenic nonhuman mammal developed from said mammalian oocyte.

31. A transgenic nonhuman mammal, characterized in that it has been generated by the process as claimed in either of claims 28 and 29.

32. A transgenic nonhuman mammal, characterized in that it is a descendent of the mammal as claimed in claim 30.

33. The use of a transgenic nonhuman mammal as claimed in any of claims 19, 30 and 31 for obtaining a nonhuman cell, a nonhuman organ-specific tissue and/or a nonhuman mammalian organ for allo- and/or xenotransplantation.

34. The use of a transgenic nonhuman mammal as claimed in any of claims 19, 30 and 31, of a human or animal organ-specific tissue and/or of a human or animal mammalian organ as claimed in claim 18 for finding pharmacologically active principles and/or for identifying toxic substances.